106TH CONGRESS 1ST SESSION

H. R. 2030

To amend title XVIII of the Social Security Act to improve the process by which the Secretary of Health and Human Services makes coverage determinations for items and services furnished under the Medicare Program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

June 7, 1999

Mr. Ramstad introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to improve the process by which the Secretary of Health and Human Services makes coverage determinations for items and services furnished under the Medicare Program, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
- 4 (a) SHORT TITLE.—This Act may be cited as the
- 5 "Medicare Patient Access to Technology Act of 1999".

1 (b) Table of Contents of

2 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Establishment of medicare advisory committees.
- Sec. 4. Annual adjustments to medicare payment systems for changes in technology and medical practice.
- Sec. 5. Process for making and implementing certain coding modifications.
- Sec. 6. Retention of HCPCS level III codes.

3 SEC. 2. FINDINGS.

- 4 Congress makes the following findings:
- (1) In order to assure genuine access of medi-5 care beneficiaries to medical technologies, the Sec-6 7 retary of Health and Human Services has an obliga-8 tion to integrate and coordinate its medical tech-9 nology coverage policy determination process with 10 agency policies and practices that govern assignment 11 of procedure codes, establishment and adjustment of 12 payment levels and groupings, and issuance of time-13 ly instructions to contractors.
 - (2) The effectiveness of the medicare program in meeting beneficiary needs is compromised if access to state-of-the-art medical care is denied as a result of ineffective agency performance in the coverage, coding, or payment processes, or in the ineffective administrative execution of medical technology decisions.
 - (3) The Secretary of Health and Human Services owes medicare beneficiaries the assurance that

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the various medicare payment systems (in both the fee-for-service and managed care areas) are operated in a way that reflects developments in, and improvements upon, medical technology by properly setting

and adjusting payment levels and payment groups.

- 6 (4) Clear, predictable, and well-functioning cov-7 erage, coding, and payment systems are particularly 8 critical to this country's small medical technology 9 companies, which are the originators of most med-10 ical product innovations.
- 11 (5) Unless medicare's coverage, coding, and 12 payment systems review products promptly, apply 13 standards appropriate for medical technology, and 14 provide reasonable reimbursement levels, these com-15 panies will experience difficulties in bringing the 16 benefits of medical innovation to medicare bene-17 ficiaries.

18 SEC. 3. ESTABLISHMENT OF MEDICARE ADVISORY COMMIT-

19 **TEES.**

- 20 (a) In General.—Title XVIII of the Social Security
- 21 Act (42 U.S.C. 1395 et seq.) is amended by adding at
- 22 the end the following new section:
- 23 "MEDICARE ADVISORY COMMITTEES
- "Sec. 1897. (a) Establishment of Medicare Ad-
- 25 VISORY COMMITTEES.—For the purpose of securing ad-
- 26 vice and recommendations on issues related to coverage,

1	payment, and coding decisions, the Secretary shall estab-
2	lish, under section 9(a)(1) of the Federal Advisory Com-
3	mittee Act, the advisory committees described in this sec-
4	tion.
5	"(b) Medicare Payment and Coding Advisory
6	COMMITTEE.—
7	"(1) Establishment.—For the purpose of se-
8	curing advice and recommendations on payment and
9	coding issues under this title, not later than January
10	1, 2000, the Secretary shall establish the Medicare
11	Payment and Coding Advisory Committee (herein-
12	after in this subsection referred to as the 'Com-
13	mittee'). The Secretary shall consult with the Com-
14	mittee, and may consult directly with any panel of
15	the Committee established pursuant to subsection
16	(d)(1).
17	"(2) Duties.—The Committee, and its panels,
18	shall provide advice and recommendations to the
19	Secretary on policies regarding payment and coding
20	issues under this title, including identification of—
21	"(A) policies and mechanisms to help en-
22	sure that payment and coding decisions are—
23	"(i) made in a way that encourages
24	access to high-quality medical care under
25	this title;

1	"(ii) made through processes that
2	allow for significant public participation;
3	and
4	"(iii) made expeditiously, in accord-
5	ance with specified time frames for each
6	significant step in the process of making
7	such decisions;
8	"(B) an equitable mechanism for deter-
9	mining fee schedule payment amounts for items
10	and services (other than physicians' services);
11	and
12	"(C) processes for reconsideration and ap-
13	peal of determinations of fee schedule payment
14	amounts.
15	"(3) Report.—
16	"(A) ANNUAL REPORT TO THE SEC-
17	RETARY.—Not later than December 1 of each
18	of fiscal years 2000 through 2003, the Com-
19	mittee shall submit to the Secretary a report on
20	the progress of the Committee progress during
21	the preceding fiscal year, in carrying out the
22	duties under paragraph (2).
23	"(B) Publication of Report.—Not later
24	than 60 days after receipt of the report under
25	subparagraph (A), the Secretary shall publish

1	the report, together with any supplemental
2	views of the Secretary, on the Internet site of
3	the Department of Health and Human Services.
4	"(4) Termination.—The Committee shall ter-
5	minate on September 30, 2003.
6	"(c) Advisory Committee on Medicare Access
7	TO TECHNOLOGY.—
8	"(1) Establishment.—Not later than July 1,
9	2003, the Secretary shall establish the Medicare Ac-
10	cess to Technology Advisory Committee (hereinafter
11	in this subsection referred to as the 'Committee').
12	The Secretary shall consult with the Committee, and
13	may consult directly with any panel of the Com-
14	mittee established pursuant to subsection $(d)(1)$.
15	"(2) Duties.—The Committee, and its panels,
16	shall provide advice and recommendations to the
17	Secretary with respect to—
18	"(A) the issues referred to the Medicare
19	Coverage Advisory Committee (established by
20	the Secretary on November 24, 1998, notice of
21	which was printed in the Federal Register on
22	December 14, 1998, (63 FR 68780));
23	"(B) the issues referred to the Medicare
24	Payment and Coding Advisory Committee
25	under subsection (b): and

"(C) integrating policies on coverage, payment, and coding under this title into a process that helps to assure timely access to high-quality medical care.

"(3) Report.—

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- "(A) ANNUAL REPORT TO THE SEC-RETARY.—Not later than December 1 of every year beginning with 2004, the Committee shall submit to the Secretary a report on the progress of the Committee during the preceding fiscal year, in accomplishing the duty described in paragraph (2)(C).
- "(B) Publication of Report.—Not later than 60 days after receipt of the report under subparagraph (A), the Secretary shall publish the report, together with any supplemental views of the Secretary, on the Internet site of the Department of Health and Human Services.
- "(4) Duration.—Section 14(a)(2)(B) of the Federal Advisory Committee Act (5 U.S.C. App.; relating to the termination of advisory committees) shall not apply to the Committee.
- 23 "(d) ADVISORY COMMITTEE PROCEDURES.—In ad-24 ministering each of the advisory committees under this 25 section, the Secretary shall—

1	"(1) organize each advisory committee into pan-
2	els of experts according to types of items or services;
3	"(2) solicit nominations as needed from the
4	public by publishing a notice in the Federal Register
5	and on the Internet site of the Department of
6	Health and Human Services;

- "(3) ensure participation on each advisory committee of persons who—
 - "(A) are experts in a variety of medical specialties and fields of science, in specific areas of medical technology (such as clinical and diagnostic tests and durable medical equipment), in medical research generally (such as the study of treatment outcomes), and in other areas relevant to the duties assigned to the advisory committee (taking into account, as appropriate, any affiliations individuals may have with organizations possessing information, expertise, and other resources that would contribute significantly to the work of the advisory committee and its panels);
 - "(B) are qualified by training and experience to evaluate the matters referred to the advisory committee (including, on each panel, a representative of consumer interests and a rep-

1	resentative of the interests of manufacturers of
2	medical technology); and
3	"(C) have adequately diversified back-
4	grounds so that the advisory committee will
5	provide balanced advice and recommendations;
6	"(4) exclude from membership on each advisory
7	committee individuals who are in the full time em-
8	ploy of the United States and engaged in the admin-
9	istration of the program established under this title;
10	"(5) limit the number of members of each advi-
11	sory committee who are otherwise in the full-time
12	employ of the United States to not more than 10
13	percent of the total membership of the advisory com-
14	mittee;
15	"(6) impose appropriate term limits for mem-
16	bers of each advisory committee;
17	"(7) designate one of the members of each
18	panel to serve as the chair thereof and appoint an
19	executive subcommittee comprised of the chairs of
20	each panel to advise the Secretary regarding—
21	"(A) establishing priorities; and
22	"(B) referring issues to appropriate panels;
23	"(8) permit each panel to independently advise
24	the Secretary with regard to matters referred to the

1	panel, without the need to obtain the concurrence
2	of the full advisory committee;
3	"(9) provide for appropriate consultation with
4	outside experts by each advisory committee and its
5	panels;
6	"(10) provide for—
7	"(A) full public participation, to the extent
8	required or permitted under law, in any meet-
9	ing of each advisory committee or its panels;
10	"(B) at least 60 days' advance notice on
11	the Internet site of the Department of Health
12	and Human Services of any such meeting, in-
13	cluding a statement of the issues to be consid-
14	ered by the advisory committee or panel, a de-
15	scription of the specific information that is rel-
16	evant to such issues, and the text of any pro-
17	posals the Secretary will ask the advisory com-
18	mittee or panel to consider;
19	"(C) consideration by each advisory com-
20	mittee or panel of relevant information or testi-
21	mony that is submitted by the public; and
22	"(D) public access in a central repository
23	to the information described in subparagraph
24	(C) at least 20 days before the meeting;

1	"(11) furnish each advisory committee and its
2	panels with adequate clerical and other necessary as-
3	sistance;
4	"(12) provide for the compensation of members
5	of each advisory committee and its panels (other
6	than those in the full time employ of the United
7	States)—
8	"(A) while attending meetings or otherwise
9	engaged in official business at rates to be fixed
10	by the Secretary, but not at rates exceeding the
11	daily equivalent of the rate in effect for level IV
12	of the Executive Schedule for each day so en-
13	gaged, including travel time; and
14	"(B) while serving away from their homes
15	or regular places of business, of travel expenses
16	(including per diem in lieu of subsistence) as
17	authorized by section 5703 of Title 5, United
18	States Code, for persons in the Government
19	service employed intermittently;
20	"(13) provide for the panels to meet at least
21	once every 3 months unless there is no business to
22	conduct;
23	"(14) require each advisory committee and its
24	panels to provide, with any recommendation, a sum-
25	mary of the reasons for the recommendation and a

1	summary of the data upon which the recommenda-
2	tion is based;
3	"(15) make a verbatim transcript of each advi-
4	sory committee and panel proceedings (other than
5	those portions that are closed to the public in ac-
6	cordance with law) available to the public within 14
7	days on an official Internet site of the Department
8	of Health and Human Services; and
9	"(16) prescribe in regulations the procedures to
10	be followed by each advisory committee and its pan-
11	els in making their reviews and recommendations.
12	"(e) Definitions.—For purposes of this section—
13	"(1) the term 'coding' means the assignment of
14	identification codes for medical equipment and sup-
15	plies, items, services, and other benefits under this
16	title; and
17	"(2) the term 'payment' means the determina-
18	tion of appropriate payment amounts for medical
19	equipment and supplies, items, services, and other
20	benefits under this title.".
21	(b) Transition, Continuing Responsibility for
22	Unfinished Duties.—
23	(1) Effective on the date the Medicare Access
24	to Technology Advisory Committee is established,
25	the Secretary of Health and Human Services shall

- provide for the transfer to such committee of any as-sets and staff of the Medicare Coverage Advisory Committee and the Medicare Payment and Coding Advisory Committee, without any loss of benefits or seniority by virtue of such transfers. Fund balances available to the Medicare Coverage Advisory Com-mittee or the Medicare Payment and Coding Advi-sory Committee for any period shall be available to the Medicare Access to Technology Advisory Com-mittee for such period for like purposes.
 - (2) The Medicare Access to Technology Advisory Committee shall be responsible for the preparation and submission of reports and recommendations not yet submitted to the Secretary by the Medicare Coverage Advisory Committee or the Medicare Payment and Coding Advisory Committee upon the expiration of those committees.

(c) Reporting Requirements.—

- (1) Not later than April 1, 2000, the Secretary of Health and Human Services shall submit to Congress a report certifying that the committee and panels required to be established by section 1897(b), as added by subsection (a), are operational.
- (2) Not later than September 1, 2003, the Secretary of Health and Human Services shall submit

- to Congress a report certifying that the committee and panels required to be established by section 1897(c), as added by subsection (a), are operational.
 - (3) Not later than December 1 of each year beginning with 2000, the Secretary of Health and Human Services shall submit to Congress a report describing the timeliness of the Secretary's national coverage policy decision making during the preceding fiscal year measured by the time frames the Secretary has published for the national coverage policy determination process, and such report shall include the actual time periods that were necessary to complete and fully implement national coverage policy determinations and each significant step in the process.
 - (4) Not later than July 1, 2000, the Secretary of Health and Human Services shall submit to Congress a report, on the nature of the coverage policy determination processes used by Medicare+Choice organizations, under part C of title XVIII of the Social Security Act, including a detailed explanation of any steps taken to ensure that the coverage policy determination processes under the Medicare+Choice program—

1	(A) produce results consistent with the
2	coverage policy determinations reached under
3	parts A and B of such title; and
4	(B) treat any medical device being inves-
5	tigated under section 520(g) of the Federal
6	Food, Drug, and Cosmetic Act (42 U.S.C.
7	360j(g)), in a manner consistent with the treat-
8	ment afforded such medical device under such
9	parts.
10	SEC. 4. ANNUAL ADJUSTMENTS TO MEDICARE PAYMENT
11	SYSTEMS FOR CHANGES IN TECHNOLOGY
12	AND MEDICAL PRACTICE.
13	(a) In General.—Title XVIII of the Social Security
14	Act (42 U.S.C. 1395 et seq.) is amended by inserting after
15	section 1888 the following new section:
16	"ANNUAL ADJUSTMENTS TO MEDICARE PAYMENT SYS-
17	TEMS FOR CHANGES IN TECHNOLOGY AND MEDICAL
18	PRACTICE
19	"Sec. 1889. (a) In General.—Notwithstanding any
20	other provision of this title, the Secretary shall adjust the
21	appropriate elements of the payment systems established
22	under sections $1833(i)(2)(A)$, $1833(t)$, 1848 , and $1886(d)$,
23	and the payment systems referred to in subsection (f), (in-
24	cluding relative payment weights, relative value units, and
25	weighting factors) at least annually to ensure that pay-
26	ments under such systems—

1	"(1) appropriately reflect changes in medical
2	technology and medical practice affecting the items
3	and services for which payment may be made under
4	such systems; and
5	"(2) promote the efficient and effective delivery
6	of high-quality health care.
7	"(b) Rules for Determining Adjustments.—
8	Except as provided in subsection (c), the provisions of sec-
9	tion $1833(i)(2)(A)$, section $1833(t)(6)$, section
10	1848(c)(2)(B), and section $1886(d)(4)(C)$, and the appro-
11	priate provisions of the payments systems referred to in
12	subsection (f), shall apply to the annual adjustments re-
13	quired by this section in the same manner and to the same
14	extent as they apply to the periodic adjustments of relative
15	payment weights, relative value units, and weighting fac-
16	tors, respectively, that are authorized or required by such
17	sections.
18	"(c) Use of Internal Data Collected by the
19	Secretary.—
20	"(1) In General.—In determining the adjust-
21	ments required by this subsection, the Secretary
22	may not—
23	"(A) decline to make an adjustment that is
24	based on data collected by the Secretary in the
25	administration of the program established

1	under this title if the data reflect a representa-
2	tive sample of cases that is statistically valid;
3	and
4	"(B) establish a uniform period of time
5	(such as one year) from which such data must
6	be drawn.
7	"(2) Deadline for supplying internal
8	DATA.—The Secretary shall establish a reasonable
9	deadline for the submission of data collected by the
10	Secretary to be used in making the adjustments re-
11	quired by this section. In no event may the deadline
12	established under this paragraph be more than 7
13	months before the first day of the provider payment
14	update period for which the adjustment or adjust-
15	ments to which the data relates would be effective.
16	"(d) Use of External Data.—
17	"(1) In general.—Subject to paragraph (2),
18	in determining the adjustments required by this sec-
19	tion, the Secretary shall utilize data other than data
20	collected by the Secretary in the administration of
21	the program established under this title if—
22	"(A) data collected by the Secretary in the
23	administration of such program are not avail-
24	able at the time such adjustments are being de-
25	termined; and

1	"(B) such other data are reliable and
2	verifiable.
3	"(2) External data facilitating the use
4	OF INTERNAL DATA.—In determining the adjust-
5	ments required by this section, the Secretary may
6	not—
7	"(A) decline to use data other than data
8	collected by the Secretary if such other data—
9	"(i) enable the Secretary to identify or
10	refine data collected by the Secretary for
11	use in making such an adjustment; and
12	"(ii) are based on a representative
13	sample of cases that is statistically valid;
14	or
15	"(B) establish a uniform period of time
16	(such as one year) from which such data must
17	be drawn.
18	"(3) Alternative sources of data.—In de-
19	termining the adjustments required by this section,
20	the Secretary shall use data, that otherwise meets
21	the requirements of this subsection, collected by (or
22	on behalf of)—
23	"(A) private payers;
24	"(B) manufacturers of medical tech-
25	nologies;

1	"(C) suppliers;
2	"(D) groups representing physicians and
3	other health care professionals;
4	"(E) groups representing providers;
5	"(F) clinical trials; and
6	"(G) such other sources as the Secretary
7	determines to be appropriate.
8	"(4) Clarification.—Nothing in this title
9	shall be construed as—
10	"(A) requiring the Secretary to identify all
11	claims submitted under a payment system es-
12	tablished under section 1833(i)(2)(A), section
13	1833(t), section 1848, or section 1886(d), or
14	under the payment systems referred to in sub-
15	section (f), involving the use of a medical tech-
16	nology before the Secretary may make the ad-
17	justments under this section (or under section
18	1833(i)(2)(A), section 1833(t), section 1848, or
19	section 1886(d), or under the appropriate sec-
20	tions with respect to the payment systems re-
21	ferred to in subsection (f)) with respect to such
22	technology; or
23	"(B) authorizing the Secretary to defer ac-
24	tion on such an adjustment until all such claims
25	are identifiable

"(5) Deadline for supplying external DATA.—The Secretary shall establish a reasonable deadline for the submission of data other than data collected by the Secretary to be used in making the adjustments required by this section. In no event may the deadline established under this paragraph be more than 9 months before the first day of the provider payment update period for which the ad-justment or adjustments to which the data relates would be effective.

"(e) Timing of Adjustments.—

- "(1) IN GENERAL.—The annual adjustments required by this section shall—
 - "(A) apply to provider payment update periods beginning on or after October 1, 2000; and
 - "(B) be described in the proposed and final rules published by the Secretary with respect to changes to a payment system established under section 1833(i)(2)(A), 1833(t), 1848, or 1886(d), or a payment system referred to in subsection (f), for the provider payment update period to which they relate, together with a description of the data on which such adjustments are based.

1	"(2) Definition.—For purposes of this sec-
2	tion, the term 'provider payment update period'
3	means—
4	"(A) in the case of the payment systems
5	established under section 1833(t) and section
6	1848, a calendar year;
7	"(B) in the case the payment systems es-
8	tablished under section 1833(i)(2)(A) and sec-
9	tion 1886(d), a fiscal year beginning on October
10	1; and
11	"(C) in the case of a payment system re-
12	ferred to in subsection (f), such calendar year
13	or such fiscal year, as determined by the Sec-
14	retary.
15	"(f) Annual Updates for Other Medicare Pay-
16	MENT Systems.—The provisions of subsection (a) shall
17	apply to payment systems established under this title
18	(other than those specified in subsection (a)) in the same
19	manner as they apply to the payment systems specified
20	in such subsection.".
21	(b) Conforming Amendments.—
22	(1) Ambulatory surgical centers.—Section
23	1833(i)(2)(A) of the Social Security Act (42 U.S.C.
24	1395l(i)(2)(A)) is amended by striking "Each" in

1 the second sentence thereof and inserting "Subject 2 to section 1889, each". 3 (2) Outpatient hospital prospective pay-4 MENT SYSTEM.—Section 1833(t)(6)(A) of such Act 5 (42 U.S.C. 1395l(t)(6)(A)) is amended by striking 6 "The" and inserting "Subject to section 1889, the". 7 (3)Physician PAYMENT.—Section 8 1848(c)(2)(B)(i) of such Act (42 U.S.C. 1395w-9 4(c)(2)(B)(i)) is amended by striking "The" and in-10 serting "Subject to section 1889, the". 11 (4) Inpatient Hospital Prospective Pay-12 MENT SYSTEM.—Section 1886(d)(4)(C)(i) of such 13 Act (42 U.S.C. 1395ww(d)(4)(C)(i)) is amended by 14 striking "The" and inserting "Subject to section 15 1889, the". 16 SEC. 5. PROCESS FOR MAKING AND IMPLEMENTING CER-17 TAIN CODING MODIFICATIONS. 18 (a) IN GENERAL.—Notwithstanding any other provi-19 sion of title XVIII of the Social Security Act (42 U.S.C. 20 1395 et seq.), the Secretary of Health and Human Serv-21 ices shall— 22 (1) accept recommendations for HCPCS level II 23 code modifications from the public throughout the 24 year;

- 1 (2) cause determinations on recommendations 2 received during the three months immediately pre-3 ceding the last month of a calendar quarter to be 4 made not later than the first day of the following 5 calendar quarter; and
- 6 (3) incorporate approved modifications to
 7 HCPCS level II codes into the payment systems es8 tablished under such title (including the medicare
 9 fee schedule data base) not later than 180 days after
 10 the date on which the determination approving a
 11 modification was made.
- 12 (b) ELIMINATION OF REQUIREMENT FOR MAR13 KETING EXPERIENCE.—Notwithstanding any other provi14 sion of title XVIII of the Social Security Act, the Sec15 retary of Health and Human Services may not require a
 16 minimum period of marketing experience with respect to
 17 a drug or device as a condition of consideration or ap18 proval of a recommendation for a HCPCS level II modi19 fication for such drug or device.
- 20 (c) Definition.—For purposes of this section, the 21 term "HCPCS level II code modification" means any 22 change to the alpha-numeric codes for items not included 23 in level I or level III of the Health Care Financing Admin-24 istration Common Procedure Coding System (HCPCS).

- 1 (d) Report.—Not later than 180 days after the date
- 2 of the enactment of this Act, the Secretary of Health and
- 3 Human Services shall submit to Congress a report on the
- 4 feasibility and desirability of opening meetings of the
- 5 Alpha-Numeric Editorial Panel of the Department of
- 6 Health and Human Services to the public. If the Secretary
- 7 determines that opening such meetings to the public is not
- 8 feasible or desirable, the Secretary shall include in the re-
- 9 port a detailed explanation of the reasons for such deter-
- 10 mination.
- 11 (e) Effective Date.—The provisions of this section
- 12 take effect on January 1, 2000.
- 13 SEC. 6. RETENTION OF HCPCS LEVEL III CODES.
- 14 (a) IN GENERAL.—The Secretary of Health and
- 15 Human Services shall maintain and continue the use of
- 16 HCPCS level III codes (as in effect on June 1, 1999),
- 17 and shall make such codes available to the public.
- 18 (b) Definition.—For purposes of this section, the
- 19 term "HCPCS Level III codes" means the alpha-numeric
- 20 codes for local use under the Health Care Financing Ad-
- 21 ministration Common Procedure Coding System
- 22 (HCPCS).

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